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| 09/694,241 | 10/23/2000 | Nicole Baric | K 168 | 9230 |
| 7590 11/18/2004 | | | | |
| PARKHURST & WENDEL 1421 PRINCE STREET SUITE 210 ALEXANDRIA, VA 22314-2805 | | EXAMINER PADMANABHAN, KARTIC | | |
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| | | 1641 | | |

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/694,241

Applicant(s)

BARIE ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3 and 6-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 3 is objected to because of the following informalities: in the second to last line of the claim, there appears to be a typographical error. It appears that applicant has recited "diazimine" instead of "diazirine." Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Chai-Gao et al. (US Pat. 5,858,802).

Swan et al. teach a process for the preparation of crosslinked matrices containing covalently immobilized chemical species and unbound releasable chemical species. According to the reference, polymers may be covalently immobilized in an insoluble 3-D crosslinked matrix, which is preferably formed as a coating upon a surface. A desired chemical species and a polymeric coupling compound such as a photoderivatized polymer having multiple photoreactive groups are brought into proximity to each other. Upon activation, binding occurs (abstract and cols. 2-3). Dextran may be the polymer from which the coupling compound is derived (col. 3, line 62). In addition, the photoreactive groups of the reference may be diazirines, such as 3-trifluoromethyl-3-phenyldiazirine (col. 5, line 55).

Hubbell et al. teach interfacial polymerization to form a membrane on the surface of a biological membrane. Tissue is directly coated with photoinitiator, which is immersed in macromer solution, and immediately irradiated. This results in a thin polymer coat (col. 9). Dextran may be the macromer of the reference (col. 11, lines 19-54). However, neither Swan et al. nor Hubbell et al. teach the use of TRIMID modification.

Chai-Gao et al. teach a method for making a device including a substrate and at least one biologically active substance bound to the surface of the substrate. The device is obtained by simultaneous or sequential reaction of the substrate and of the substance with a bifunctional

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coupling agent in which one of the functional groups may be photoactivated. The photoactivator is preferably a TRIMID-modified protein, such as T-BSA (cols. 3-5).

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator of Chai-Gao et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Chai-Gao et al. as the photoinitiator, with the only difference being that the diazirine in Chai-Gao et al. is substituted. Since the diazarines of Chai-Gao et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazarine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would have further been obvious to use TRIMID-modified aminodextran instead of T-BSA because, as applicant admits (page 3 of response), both polymers carry amino groups that are derivatized with TRIMID, and the "person of ordinary skill in the art would have no difficulty in accepting readily and understanding easily that the same type of reactions can take place on the amino groups of these two polymers."

6. Claims 3 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan et al. (US Pat. 5,563,056) or Hubbell et al. (US Pat. 5,529,914) in view of Wessa et al. (WO 97/43631)

Swan et al. and Hubbell et al. teach coating processes, as previously discussed. However, the references do not teach TRIMID modification, the use of BSA or polyimide, or application to biological sensors.

Wessa et al. teach a process for producing a sensor for detecting proteins. The sensor consists of a sensor body, one surface of which is coated with a polymer layer with receptor

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molecules bonded to said polymer layer. The bond between the polymer and the receptor molecules is provided by a photoreactive molecule that is covalent to the lysine of a receptor molecule and inserted into the polyimide. The photoreactive molecule is preferably TRIMID. The modified protein, which may be T-BSA, is bound to the polymer layer by UV irradiation. The sensor of the reference may be used as a surface acoustic wave sensor, which is interpreted as an electromechanical sensor. In addition, wave sensors are also interpreted as mass sensitive, as a difference in mass on the sensor will affect the results in some manner.

It would have been *prima facie* obvious to use the TRIMID-modified photoinitiator and polyimide of Wessa et al. with the method of Swan et al. or Hubbell et al. because Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Wessa et al. as the photoinitiator, with the only difference being that the diazirine in Chai-Gao et al. is substituted. Since the diazarines of Wessa et al. and Swan et al. both function as photoinitiators, it would have been obvious to use any diazarine with the method of Swan et al. or Hubbell et al. with a reasonable expectation of success. It would have further been obvious to use TRIMID-modified aminodextran instead of T-BSA because, as applicant admits (page 3 of response), both polymers carry amino groups that are derivatized with TRIMID, and the "person of ordinary skill in the art would have no difficulty in accepting readily and understanding easily that the same type of reactions can take place on the amino groups of these two polymers."

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Response to Arguments

7. Applicant's arguments filed 11/2/04 have been fully considered and are persuasive to overcome Sigrist, but they are not persuasive to overcome the remaining rejections under 35 USC 103.
8. Applicant's position that their argument with respect to T-BSA and TRIMID-modified aminodextran that a "person of ordinary skill in the art would have no difficulty in accepting readily and understanding easily that the same type of reactions can take place on the amino groups of these two polymers" is not an admission of obviousness is off point. In the examiner's view, applicant's statement is not an explicit admission that the claimed subject matter is obvious; however, applicant's admission makes clear that one of skill in the art at the time of the invention would have had the requisite skill, knowledge, and motivation to use TRIMID-modified aminodextran instead of T-BSA with a reasonable expectation of success.
9. Applicant's arguments with respect to the alleged advantages of the present invention over the prior art are moot, as the examiner maintains that the combination of references teaches the claimed invention, and as such, would possess the same features as the present invention. In addition, there is no actual showing or evidence to support the alleged advantages of the present invention. Further, since, in traversing the rejections based upon Swan or Hubbell in view of Chai-Gao or Wessa, applicant has relied primarily on the arguments presented in the response filed on May 24, 2004, the examiner's responses to those arguments are reproduced below in paragraphs 10-13, as the examiner's position with respect to those arguments remains unchanged.

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10. Applicant's argument that Swan does not teach a conventional substrate is irrelevant, as such is not required in the claims, and the prior art need not teach that substrate depicted in Applicants' figure 1. Applicant's arguments that Swan does not teach the use of a protein are accurate; however, Chai-Gao or Wessa as secondary references have been relied upon for this feature. Applicant's arguments that Swan does not teach dextran alone as the material to be connected are erroneous. It is first noted that applicant's arguments distinguish between a coupling compound and the compound to be coupled, a distinction that does not appear anywhere in the claims. Rather, the claims merely require co-immobilization of a TRIMID-protein and dextran. Swan clearly teaches co-immobilization of a chemical species and the coupling compound (Col. 3, lines 29-30). The coupling compound may be dextran (Col. 3, line 62). While the coupling compound of the reference may indeed be different than the coupling compound of the present invention, as long as dextran is co-immobilized with a protein (taught by secondary ref.), the claim limitations are deemed met, as the claims do not require the "coupling compound" to be the protein. Applicant's argument that the examiner's statement that dextran is the polymer from which the coupling compound is derived demonstrates the lack of pertinence of the reference is not convincing, as the claims do not state which component is used for coupling and which is coupled, but merely requires coimmobilization.

11. In terms of the Hubbell reference, applicant argues that the reference does not teach dextran. While this may be true, the claims only generically refer to dextran and do not exclude derivatives of dextran. In addition, even if derivatives of dextran were excluded from the claims (which they haven't been), the use of dextran as a substitute for dextran derivatives would be viewed as a matter of optimization, which would have been obvious to one of ordinary skill in

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the art at the time of the invention (absent compelling evidence to the contrary). The examiner agrees that the reference does not teach the use of a modified protein as a photolinker, but Chai-Gao has been relied upon to cure this deficiency. It is also once again noted that there is no distinction in the claims between the component to be coupled, and that which facilitates the coupling. Applicant's arguments with respect to Chai-Gao are based on the premise that the reference does not teach immobilization of dextran; however, as a secondary reference, it is only relied upon for teaching a TRIMID-protein used in immobilization and is not required to teach every element of the claims.

12. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Hubbell et al. states that virtually any photoinitiator can be used with the method of their reference, and Swan et al. uses a similar diazirine to that of Chai-Gao et al. as the photoinitiator, with the only difference being that the diazirine in Chai-Gao et al. is substituted.

13. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the

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applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

Claims 3 and 6-10 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

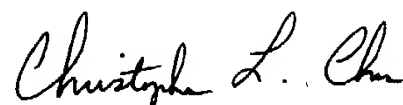
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800-1641

11/14/04